84/9/2/54

WO 2005/027875

BEST AVAILABLE COPY

AP20 TO MAIN SOUD

PCT/US2004/030724

[received by the International Bureau on 22 APR 2005 (22.04.05); original claims 1 and 20 have been replaced by amended claims 1 and 20 (2 pages)]

What is claim is:

- Particles for drug delivery by inhalation, comprising at least one active ingredient 1. which is non-crystalline, wherein the outer surface of the particles is substantially smooth.
- Particles according to Claim 1, further comprising a second or more active(s) and/or 2 one or more extipients.
- Particles for drug delivery according to Claim 1 or Claim 2, the particles containing a 3. plurality of active ingredients which active ingredients are non-crystalline.
- Particles according to Claim 3, the outer surface of the particles being substantially 4 smooth.
- 5. Particles according to Claim 3, the particles being substantially spherical.
- Particles according to Claim 5, the particles being oblate spheroidal. 6.
- 7. Particles according to Claim 3, the particles being substantially oval.
- 8. Particles according to Claim 3, the particles being substantially elliptical.
- 9. Particles according to any preceding claim, having a particle size in the range 0.5 µm - 5 μm.
- 10. Particles according to Claim 9, the particle size being between 1 µm to 3 µm.
- 11. Particles according to Claim 9 when dependent on Claim 7 or Claim 8, the longer axis of an oval or elliptical particle having a length between 1 μm to 3 μm .
- 12. Particles according to any preceding Claim, the particles being electrically uncharged.
- 13. Particles according to any preceding claim, provided by a method selected from the group compilising rapid expansion of supercritical solutions, precipitation from gas saturated solutions, gas anti-solvent systems, aerosol solvent extraction systems and spray drying processes.
- 14. Particles according to any preceding claim, there being from two to four active ingredients.

BEST AVAILABLE COPY

WO 2005/027875 PCT/US2004/030724

15. Particles according to any preceding claim, comprising a pharmaceutically acceptable particular excipient or excipients.

- 16. Particles according to any preceding claim, the active ingredients comprising a B2 agonist and a steroid.
- 17. Particles according to Claim 15, comprising fluticasone-dipropionate and salmeterol xinafoate.
- 18. Particles according to any one of Claims 1 to 15, comprising formaterol and budesonide.
- 19. Particles for drug delivery according to any of daims 2 to 18, the or each excipient being soluble in conditions obtaining in the nose, lung(s) or mouth of a human or animal.
- 20. An inhalation composition, comprising particles which incorporate at least one active ingredient which is non-crystalline, wherein the particles have an outer surface that is substantially smooth.
- 21. A composition according to Claim 20, further comprising a second or more active(s) and/or one or more excipients.
- 22. A composition according to Claim 20 or 21, the particles containing a plurality of active ingredients, which active ingredients are non-crystalline.
- 23. A composition according to Claims 20 to 22, there being from two to four active ingredients.
- 24. A composition according to any of Claims 21 to 23, the particles comprising a pharmaceutically acceptable excipient within the particle.
- 25. A composition according to any of Claims 21 to 24, the particles comprising a pharmaceutically acceptable excipient or excipients where a main excipient is in a greater proportion than the active or actives.
- A composition according to Claim 25, the main excipient being Mannitol or PVP.
- 27. A composition according to any of Claims 21 to 26, comprising one or more additional carrier exciplent(s).